



Reference: FOI # 2018-759

3/19/2018

Anthony Roberts
411A Highland Ave, DEPT MR 47998
Somerville, MA 02144-2516

Via email: 47998-19268692@requests.muckrock.com

Dear Requestor,

The attached record(s) are being provided by the Office of Regulatory Affairs (ORA) Division of Information Disclosure Policy –SAN FRANCISCO Queue in response to your request 2018-759 for record(s) from the Food and Drug Administration pursuant to the Freedom of Information Act regarding:

IRONMAG LABS- WARNING LTR 10/23/17

Your request is granted in part.

After a thorough review of the responsive records, we have determined that portions of the documents are exempt from disclosure under FOIA exemptions (b)(4) of the FOIA 5 U.S.C. § 552, as amended and delineated below:

- Exemption (b)(4) permits the withholding of “trade secrets” (TS) and “commercial confidential information” (CCI). Disclosure of this information would impair the government’s ability to obtain necessary information in the future and cause substantial harm to the competitive position of the person from whom the information was obtained. Under the balancing test of this exemption, we are withholding all proprietary information identified as TS and CCI.

San FRANCISCO OFFICE considers your request closed. If you have any questions about this response, you may contact Tracey Taylor at 214-253-5294 or Traceyd.taylor@fda.hhs.gov.

You have the right to appeal this determination. By filing an appeal, you preserve your rights under FOIA and give the agency a chance to review and reconsider your request and the agency’s decision.

Your appeal must be mailed within 90 days from the date of this response, to:

U.S. Food and Drug Administration
5630 Fishers Lane, Room 1035
Rockville, MD 20857
www.fda.gov



Ms. Catherine Teti
Deputy Agency Chief FOIA Officer
U.S. Department of Health and Human Services
Office of the Assistant Secretary for Public Affairs
Room 729H
200 Independence Avenue, S.W.
Washington, DC 20201

Please clearly mark both the envelope and your letter "Freedom of Information Act Appeal."

If you would like to discuss our response before filing an appeal to attempt to resolve your dispute without going through the appeals process, please contact:

Division of Freedom of Information
U.S. Food & Drug Administration
5630 Fishers Lane, Room 1035
Rockville, MD 20857
PHONE: 301-796-3900
FAX: 301-827-9267

You may also contact the FDA FOIA Public Liaison for assistance at:

U.S. Food & Drug Administration
Office of the Executive Secretariat
5630 Fishers Lane, Room 1035
Rockville, MD 20857
EMAIL: FDAFOIA@fda.hhs.gov

If you are unable to resolve your FOIA dispute through our FOIA Public Liaison, the Office of Government Information Services (OGIS), the Federal FOIA Ombudsman's office, offers mediation services to help resolve disputes between FOIA requesters and Federal agencies. The contact information for OGIS is:

Office of Government Information Services
National Archives and Records Administration
8601 Adelphi Road—OGIS
College Park, MD 20740-6001
Telephone: 202-741-5770
Toll-Free: 1-877-684-6448

U.S. Food and Drug Administration
5630 Fishers Lane, Room 1035
Rockville, MD 20857
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E-mail: ogis@nara.gov
Fax: 202-741-5769

Please do not submit payment until you receive an invoice. The following charges for this request to date may be included in a monthly invoice:

Reproduction=\$0.00 Search=\$11.50 Review \$11.50 Other \$0.00 Total=\$23.00

Sincerely,

Tracey D. Taylor
Legal Instruments Examiner
FOIA West
Division of Information Disclosure Policy
Office of Strategic Planning and Operational Policy
Office of Regulatory Affairs
U.S. Food and Drug Administration
4040 N. Central Expressway, Suite 300
Dallas, TX 75204
T: 214-253-5294
Traceyd.taylor@fda.hhs.gov

Enclosures:

Ironmag, Response Letter (1 pg)
Ironmag, FDA Response Letter (3 pgs)
Ironmag, Response Letter (1 pg)

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